

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

NOVO NORDISK A/S AND NOVO  
NORDISK INC.,

Plaintiffs,

v.

DOCERE HOLDINGS LLC D/B/A  
DOCERE MEDICAL AND  
AESTHETIC CENTER

Defendant.

Case No. 1:25-cv-1040

**COMPLAINT**

Plaintiffs Novo Nordisk A/S (“NNAS”) and Novo Nordisk Inc. (“NNI”) (collectively, “Plaintiffs” or “Novo Nordisk”) file their complaint against Docere Holdings LLC d/b/a Docere Medical and Aesthetic Center (“Defendant”) for false advertising and unfair and deceptive trade practices, and seek monetary, injunctive, and other relief. Plaintiffs allege as follows on actual knowledge with respect to themselves and their own acts and on information and belief as to all other matters.

**INTRODUCTION**

1. Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat chronic diseases like diabetes and obesity.
2. The development of semaglutide is an example of Novo Nordisk’s commitment to innovation for those living with chronic diseases.
3. Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk’s three prescription-only medicines approved by the Food and Drug Administration (“FDA”): Ozempic® (semaglutide) injection and Rybelsus® (semaglutide) tablets

for adults with type 2 diabetes and Wegovy<sup>®</sup> (semaglutide) injection for chronic weight management.

4. Novo Nordisk is the only company in the United States with FDA-approved medicines containing semaglutide.

5. Novo Nordisk is also the only company authorized to identify its FDA-approved semaglutide medicines using the trademarks Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup>.

6. The FDA has not approved any generic versions of semaglutide medicines. To the contrary, the FDA has sent warning letters to companies that claimed that their Unapproved Products have the “same active ingredient as Ozempic, Rybelsus, and Wegovy,” noting that Ozempic and Wegovy are the only “two injectable semaglutide products FDA-approved for the U.S. market.”<sup>1</sup>

7. Novo Nordisk brings this action pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, and related state laws arising out of Defendant’s acts of false advertising and unfair and deceptive trade practices.

8. Defendant markets and sells to patients compounded drug products that purport to contain semaglutide.

9. Even though such compounded drug products have not been evaluated by the FDA for their safety, effectiveness, or quality, Defendant falsely and misleadingly represents to patients that its products are FDA-approved or the same as, or equivalent to, Novo Nordisk’s FDA-approved semaglutide medicines.

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<sup>1</sup> FDA – Warning Letter to Ozempen.com, MARCS-CMS 684435 — JUNE 24, 2024, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ozempencom-684435-06242024#:~:text=WARNING%20LETTER&text=As%20discussed%20below%2C%20FDA%20has,new%20drugs%20and%20misbranded%20drugs.>

10. Defendant's conduct is likely to confuse and deceive patients into mistakenly believing that they are purchasing authentic Novo Nordisk medicines or medicines that have been evaluated by the FDA, studied in clinical trials, and deemed safe and effective.

### **THE PARTIES**

11. Plaintiff NNAS is a corporation organized and existing under the laws of the Kingdom of Denmark and has its principal place of business in Bagsværd, Denmark. NNAS developed the Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines and has granted to NNI exclusive rights to market, advertise, promote, offer for sale, and sell Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines in the United States.

12. Plaintiff NNI is an indirect, wholly-owned subsidiary of NNAS, organized and existing under the laws of Delaware and has its principal place of business in Plainsboro, New Jersey. NNI promotes, offers, and sells Novo Nordisk's Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines throughout the United States, including in this District.

13. Defendant Docere Holdings LLC d/b/a Docere Medical and Aesthetic Center is an Ohio limited liability company with a registered business address at 10633 Pearl Road, Suite #2, Strongsville, Ohio 44138, in this judicial district.

14. Defendant sells and promotes compounded drug products that purport to contain semaglutide, but that have not been approved by the FDA ("Unapproved Compounded Drugs").

15. Defendant falsely claims or otherwise misleadingly suggests that its Unapproved Compounded Drugs are the same as or equivalent to the Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines.

### **JURISDICTION AND VENUE**

16. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 35 U.S.C. § 1121 and 28 U.S.C. § 1338(a).

17. The Court has supplemental jurisdiction over the state law cause of action pleaded herein pursuant to 28 U.S.C. § 1338(b).

18. Defendant is subject to personal jurisdiction in this District because Defendant is an Ohio-registered company and has a principal place of business in Ohio.

19. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant operates in this District, manufactures or sells its compounded drug products that purport to contain semaglutide in this District, and otherwise conducts business in this District.

### **FACTS ENTITLING NOVO NORDISK TO RELIEF**

#### **A. Novo Nordisk's FDA-Approved Semaglutide Medicines and Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> Trademarks**

20. Novo Nordisk uses the trademarks “Ozempic,” “Wegovy,” and “Rybelsus” to identify and promote the FDA-approved Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines.

21. The Ozempic<sup>®</sup> medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise.

22. The Ozempic<sup>®</sup> medicine also lowers the risk of major cardiovascular events such as stroke, heart attack, or death in adults with type 2 diabetes and known heart disease as well as the risk of kidney failure and death from cardiovascular disease in adults with type 2 diabetes and chronic kidney disease.

23. The Wegovy<sup>®</sup> medicine is indicated to reduce body weight and maintain weight reduction in obese adults and children aged 12 years and older and adults with weight-related medical problems, along with a reduced calorie diet and increased physical activity.

24. The Wegovy<sup>®</sup> medicine is also indicated, with a reduced calorie diet and increased physical activity, to reduce the risk of adverse cardiovascular events such as

“cardiovascular” death, heart attack, or stroke in adults with heart disease and who are either obese or overweight.

25. The Rybelsus<sup>®</sup> medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise.

26. The Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines have been studied in clinical trials and are FDA-approved.

27. Each of the Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines has a unique safety and efficacy profile which is set forth in its respective product label.

28. The Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines are prescription-only medicines that should only be prescribed in direct consultation with, and under the supervision of, a licensed healthcare professional.

**B. Defendant’s Sale of Unapproved Compounded Drugs**

29. Defendant markets and sells to patients Unapproved Compounded Drugs that purport to contain semaglutide.

30. The FDA has not approved Defendant’s Unapproved Compounded Drugs.

31. On information and belief, the Unapproved Compounded Drugs sold by Defendant are made by compounding pharmacies, which deliver them either directly to patients or to Defendant for administration or dispensing to patients.

32. According to the FDA, compounding is a “practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.”<sup>2</sup>

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<sup>2</sup> Human Drug Compounding, <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding>.

33. Compounded drugs are not FDA-approved.<sup>3</sup>

34. Because the FDA does not approve compounded drugs, the “FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients.”<sup>4</sup>

35. The FDA has advised that compounded drugs “do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks.”<sup>5</sup>

36. As the FDA has explained, “[c]ompounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness. Compounded drugs should only be used for patients whose medical needs cannot be met by an available FDA-approved drug.”<sup>6</sup>

37. The process to produce the compounded semaglutide drug products sold by Defendant is fundamentally different from the process used to produce the semaglutide in Novo Nordisk’s FDA-approved medicines.

38. Novo Nordisk manufactures the semaglutide in its medicines, pursuant to its FDA approval, in yeast cells under a closely controlled multistep process that uses recombinant DNA technology.

39. Upon information and belief, the compounded semaglutide drug products sold by Defendant, however, are made with a “semaglutide” manufactured via chemical synthesis.

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<sup>3</sup> Compounding Laws and Policies, <https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies>.

<sup>4</sup> *Id.*

<sup>5</sup> Compounding and the FDA: Questions and Answers, <https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers>.

<sup>6</sup> FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, [https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded?utm_medium=email&utm_source=govdelivery).

40. The chemical synthesis process, which is not used for the semaglutide in any FDA-approved semaglutide medicines, has resulted in new impurities, higher levels of known impurities, immunogenicity concerns, and potential stability issues in tested samples of compounded “semaglutide.”<sup>7</sup>

41. The FDA has received reports of adverse events, some requiring hospitalization, related to overdoses from dosing errors associated with compounded “semaglutide” products.<sup>8</sup> In several instances, patients mistakenly administered five to 20 times more than the intended dose of compounded “semaglutide.”

42. The FDA has stated that the containers and packaging (including multidose vials) used by compounders, the varying product concentrations, and the instructions accompanying the compounded drug contribute to the potential medical errors.

43. A publication from the Journal of the American Pharmacists Association also highlighted errors where patients accidentally self-administered doses of compounded “semaglutide” up to ten times greater than the prescribed amount.<sup>9</sup>

44. FDA has issued guidance on its “Concerns with Unapproved GLP-1 Drugs Used for Weight Loss,” which provides that: (1) “compounded drugs are not FDA-approved”; (2) use of compounded drugs containing “semaglutide” “can be risky for patients, as unapproved versions do not undergo FDA’s review for safety, effectiveness and quality”; and (3) “FDA has

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<sup>7</sup> Morten Hach *et al*, Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-On GLP-1 Polypeptide Drugs, Pharm. Res., (Oct. 8, 2024), *available at* <https://pubmed.ncbi.nlm.nih.gov/39379664/>.

<sup>8</sup> FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, <https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded>.

<sup>9</sup> Joseph E. Lambson et al, *Administration Errors of Compounded Semaglutide Reported to a Poison Control Center—Case Series*, 63 J. Am. Pharmacists Assc’n 5 (2023), *available at* [https://www.japha.org/article/S1544-3191\(23\)00231-5/abstract](https://www.japha.org/article/S1544-3191(23)00231-5/abstract).

received reports of adverse events related to compounded versions of semaglutide . . . .

However, federal law does not require state-licensed pharmacies that are not outsourcing facilities to submit adverse events to FDA so it is likely that adverse events from compounded versions of these drugs are underreported.”

C. Defendant’s False Advertising of Unapproved Compounded Drugs

45. Despite the foregoing, Defendant has made and continues to make false and misleading representations to patients regarding its Unapproved Compounded Drugs.

46. Defendant has promoted and continues to promote its Unapproved Compounded Drugs in connection with its operation and advertisement of its nonsurgical weight loss program, including on its website.

47. On its website, Defendant claims or implies that its Unapproved Compounded Drugs have been approved by the FDA or have been reviewed by the FDA for safety, effectiveness, and quality.

48. Defendant claims on its website that “the FDA approved Semaglutide for type 2 diabetes.”

## Semaglutide for Weight Loss in Non-Diabetics

Back in 2017, the FDA approved Semaglutide for type 2 diabetes, and it became a popular solution for managing blood sugar. Semaglutide mimics the glucagon-like peptide-1 (GLP-1) hormone that the gut releases in response to eating. One of the main roles of GLP-1 is to prompt insulin production to reduce glucose. In lower amounts, this is an excellent way to manage type 2 diabetes.

49. Defendant also claims on its website that “Semaglutide is the first drug since Saxenda (which received FDA approval in 2014) to have approval for chronic weight management.”

Semaglutide is the first drug since Saxenda (which received FDA approval in 2014) to have approval for chronic weight management.



50. Defendant further claims on its website that “Semaglutide has also been FDA-approved since 2021 for long-lasting weight control, reducing inflammation, and regulating both blood sugar and insulin levels.”

Chronic weight management is not something you need to deal with on your own. While it's been useful for more than 15 years in treating diabetes, Semaglutide has also been FDA-approved since 2021 for long-lasting weight control, reducing inflammation, and regulating both blood sugar and insulin levels. Find out if it's the choice for your body.

51. Defendant claims on its website that its Unapproved Compounded Drugs contain the same semaglutide that the FDA evaluated in the context of reviewing and approving Novo Nordisk’s new drug applications for the Wegovy<sup>®</sup>, Ozempic<sup>®</sup>, and Rybelsus<sup>®</sup> medicines.

52. Defendant’s statements regarding Plaintiff’s FDA-approved medicines appear in the context of discussing Defendant’s Unapproved Compounded Drugs.

53. Defendant has falsely advertised and continues to falsely advertise its Unapproved Compounded Drugs by making statements that describe the Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines but that are false or misleading when in reference to Defendant’s Unapproved Compounded Drugs.

54. Contrary to Defendant’s representations, the FDA has not approved a “semaglutide” peptide generally. Instead, the FDA has approved three of Novo Nordisk’s complete medicines, which contain semaglutide for the specific indications outlined in the preceding paragraphs.

55. Defendant’s false representations mislead customers into believing, incorrectly, that the product with “semaglutide” offered by Defendant has been reviewed and approved by the FDA for safety and effectiveness.

56. The FDA has not reviewed the “semaglutide” allegedly in Defendant’s Unapproved Compounded Drugs for safety, effectiveness, or quality, or otherwise as equivalent in safety, effectiveness, or quality to Novo Nordisk’s medicines.

57. Defendant claims or implies on its website that its Unapproved Compounded Drugs have been subjected to clinical studies and trials or have otherwise achieved therapeutic outcomes attributable to the Wegovy®, Ozempic®, and Rybelsus® medicines.

58. In promotional materials on its website, Defendant refers to studies that prove efficacy: “A recent study shows an improvement in body weight for most PCOS patients taking Semaglutide, as about 80% saw at least a 5% decrease.”

### Semaglutide for PCOS: Does it Help?

Many women with PCOS are obese as there are metabolic and hormonal issues present that influence weight gain. The challenging part is that this predisposition to weight gain can only make PCOS symptoms worse.

A recent [study shows](#) an improvement in body weight for most PCOS patients taking Semaglutide, as about 80% saw at least a 5% decrease. Obesity is more common among those with PCOS than those without it. Since lifestyle modifications that include diet and exercise are among the first steps toward improving long-term prognosis, a program that includes Semaglutide can work wonders.

59. Defendant also claims on its website that “studies have shown that weekly Semaglutide injections are more effective than daily injections of other weight-loss medications. Hundreds of participants noticed more significant weight loss (-15.8%) with Semaglutide as opposed to -6.4% with Liraglutide.”

Studies have shown [that weekly Semaglutide injections are more effective than daily injections of other weight-loss medications](#). Hundreds of participants noticed more significant weight loss (-15.8%) with Semaglutide as opposed to -6.4% with Liraglutide.

60. Defendant further claims on its website that “a 2022 study shows a total body weight loss percentage of 5.9% at three weeks and 10.9% at six months in patients with obesity.”

## Average Weight Loss on Semaglutide

Once you have your eating plan figured out, it's time to watch the scale drop. Many people are curious about how much weight they can expect to lose with Semaglutide. It is important to remember that exact results will vary per person.\* Your blood sugar levels should decline within the first week of using Semaglutide. The full effects can take more than eight weeks since this is a long-acting medication. A 2022 study shows a total [body weight loss percentage](#) of 5.9% at three weeks and 10.9% at six months in patients with obesity.

61. Each of the claims, implications, or representations about clinical trials of the “semaglutide” product sold by Defendant in the preceding paragraphs 58–60 is false, misleading, or both.

62. On information and belief, Defendant has not conducted any placebo-controlled or clinical studies on its Unapproved Compounded Drugs and is instead falsely and misleadingly referring to studies of Novo Nordisk’s FDA-approved medicines to promote its Unapproved Compounded Drugs.

63. On information and belief, Defendant has engaged in and continues to engage in these unlawful practices to attract customers and generate revenues and profits.

64. Defendant’s false and misleading statements and practices are likely to have caused and continue to cause mistake and deception in the marketplace.

65. Defendant’s false and misleading marketing is also likely to have exposed and continue to expose patients to unnecessary risks. Patients who mistakenly believe Defendant to be offering Novo Nordisk’s FDA-approved medicines, or equivalent thereto, are unlikely to understand the unique risks associated with, or the lack of clinical trials or testing establishing the safety and effectiveness of, Defendant’s Unapproved Compounded Drugs.<sup>10</sup>

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<sup>10</sup> See, e.g., Dozens Say They Lost Eyesight After Routine Surgery Using Compounded Pharmacy Drugs, WFAA, <https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097> (reporting mistaken belief of patient taking a compounded drug that “every pill you take, every shot you take is tested.”); FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, <https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health->

66. On information and belief, unless enjoined by this Court, Defendant will continue to falsely advertise its products as being, equivalent to, or associated with the Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, and Rybelsus<sup>®</sup> medicines, all in violation of Plaintiffs' rights.

67. On information and belief, unless enjoined by this Court, Defendant's conduct will continue to cause mistake and deception.

### **FIRST CAUSE OF ACTION**

#### **Defendant's False and Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B)**

68. Novo Nordisk realleges and incorporates each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

69. Defendant's practices, as described in this Complaint, constitute unfair competition and false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

70. Defendant has violated the Lanham Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and qualities of Defendant's business practices and products, as set forth above.

71. Defendant also engages in other false or misleading advertising and promotion intended to assure patients that Defendant's practices are lawful. On information and belief, Defendant provides patients who purchase Defendant's Unapproved Compounded Drugs (or

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care-providers-compounders-and-patients-dosing-errors-associated-compounded?utm\_medium=email&utm\_source=govdelivery ("Compounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness.")).

whom Defendant is trying to persuade to purchase its drugs) information that makes several false or misleading statements, including those described herein.

72. The above-described acts of Defendant, if not enjoined by this Court, are likely to deceive members of the general public.

73. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs.

74. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

75. By reason of Defendant's acts as alleged above, Plaintiffs have suffered and will continue to suffer injuries, including injury to Plaintiffs' business reputation.

76. Because Plaintiffs' remedies at law are not adequate to compensate for all the injuries inflicted by Defendant. Accordingly, Plaintiffs are entitled to entry of preliminary and permanent injunctive relief requiring Defendant to cease its false and misleading advertising and promotion and unfair competitive practices.

77. Because the above-described acts of Defendant are willful, Plaintiffs are entitled to disgorgement of defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117.

78. This is an exceptional case, making Plaintiffs eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

## **SECOND CAUSE OF ACTION**

### **Deceptive and Unfair Trade Practices in Violation of Ohio R.C. 4165.01 *et seq.***

79. Novo Nordisk realleges and incorporates each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

80. The above-described acts of Defendant constitute deceptive trade practices in violation of Ohio law.

81. Specifically, Defendant's acts in representing that its goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that Defendant has a sponsorship, approval, status, affiliation, or connection that it does not have are in violation of R.C. 4165.02(A)(7) and are likely to mislead consumers as to the standard, quality, or grade of Defendant's products in violation of R.C. 4165.02(A)(9).

82. Defendant has irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

83. Because Plaintiffs' remedies at law are not adequate to compensate for the injuries inflicted by Defendant, the Court should enter preliminary and permanent injunctive relief, in addition to awarding damages and attorney's fees.

### **REQUEST FOR RELIEF**

WHEREFORE, Plaintiffs request judgment against Defendant as follows:

1. That the Court enter a judgment against Defendant that Defendant has:
  - a. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a);
  - b. Engaged in unfair and deceptive trade practices under Ohio's Deceptive Trade Practices laws, Ohio R.C. 4165.01 *et seq.*
2. That the Court declare that each of the above acts was willful.
3. That the Court preliminarily and permanently enjoin and restrain Defendant and its agents, servants, employees, successors, and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with Defendant, from:

- a. falsely claiming or otherwise misleadingly suggesting that its Unapproved Compounded Drugs are the same as or equivalent to the Ozempic®, Wegovy®, and Rybelsus® medicines;
- b. advertising, stating, or suggesting that any Unapproved Compounded Drugs, including any Unapproved Compounded Drugs that either are available, directly or indirectly, from or through Defendant or the use of which or access to which is facilitated by, or with the involvement of, Defendant:
  - i. are, or contain, genuine or authentic Novo Nordisk Ozempic®, Wegovy®, or Rybelsus® medicines;
  - ii. are sponsored by or associated with Novo Nordisk;
  - iii. are approved by the FDA; have been reviewed by the FDA for safety, effectiveness, or quality; or have been demonstrated to the FDA to be safe or effective for their intended use;
  - iv. achieve or have been shown or proven to achieve therapeutic results, effects, or outcomes, including but not limited to by relying on or making reference to clinical trial results for Novo Nordisk's medicines;
  - v. achieve or have been shown or proven to achieve therapeutic results, effects, or outcomes similar or identical to Novo Nordisk's medicines or are interchangeable with or equivalent to genuine Novo Nordisk medicines;
  - vi. are associated or connected in any way with Novo Nordisk or Novo Nordisk's medicines; or

vii. contain any ingredient (including semaglutide) that is supplied by Novo Nordisk, is approved by the FDA, or is the same as any ingredient in any Novo Nordisk medicine.

- c. engaging in unfair and deceptive trade practices with respect to Novo Nordisk's Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, or Rybelsus<sup>®</sup> medicines; and
- d. engaging in deceptive acts or practices with respect to Novo Nordisk's Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, or Rybelsus<sup>®</sup> medicines.

4. That the Court require Defendant to disclose conspicuously and prominently in any public-facing materials for any Unapproved Compounded Drugs, including all advertising, marketing, and promotional materials, that: (a) the Unapproved Compounded Drugs are compounded drugs that have not been approved by the FDA; have not been reviewed by the FDA for safety, effectiveness, or quality; and have not been demonstrated to the FDA to be safe or effective for their intended use; (b) the processes by which the compounded drugs are manufactured have not been reviewed by the FDA; and (c) FDA-approved medicines containing semaglutide are available.

5. That the Court award Plaintiffs monetary relief in the form of disgorgement of Defendant's profits for Defendant's false advertising and unfair and deceptive trade practices with respect to Novo Nordisk's Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, or Rybelsus<sup>®</sup> medicines and that this monetary relief be trebled due to Defendant's willfulness, in accordance with 15 U.S.C. § 1117 and any applicable state laws.

6. That the Court order Defendant to account for and disgorge to Plaintiffs all amounts by which Defendant has been unjustly enriched by reason of Defendant's unlawful actions with respect to Novo Nordisk's Ozempic<sup>®</sup>, Wegovy<sup>®</sup>, or Rybelsus<sup>®</sup> medicines.



7. That the Court award Plaintiffs punitive damages by reason of Defendant's willful unlawful actions with respect to Novo Nordisk's Ozempic®, Wegovy®, or Rybelsus® medicines.

8. That the Court award Plaintiffs pre-judgment and post-judgment interest on all damages.

9. That the Court award Plaintiffs their reasonable attorneys' fees pursuant to 15 U.S.C. § 1117 and any other applicable provision of law.

10. That the Court award Plaintiffs the costs of suit incurred herein.

11. That the Court grant such other or further relief as the Court may deem just and proper.

May 21, 2025

Respectfully submitted,

By: /s/ Gregory J. Krabacher

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